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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/190,138	11/12/98	BOSCH H	029318/0109

HM22/0827

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WASHINGTON DC 20007-5109

EXAMINER	
WARE, T	

ART UNIT	PAPER NUMBER
1615	16

DATE MAILED: 08/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/190,138	Applicant(s) BOSCH ET AL.	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-36,40-45,47-49 and 51-117* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-36, 40-45, 47-49, 51-117* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The request filed on 6-5-01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/190,138 is acceptable and a CPA has been established. An action on the CPA follows. Also, request for extension of time (granted) filed 6-5-01 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 14, 25, 43, 67-68, 71, 73, 75, 77, 79, 81, 83, 97, and 104-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the

claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 14, 25, 71, 73, 75, 77, 79, 81, 83, 97, 104, and 111 recite the broad recitation asthma therapies, and the claims also recite bronchodilators which is the narrower statement of the range/limitation. These claims also recite the broad recitation analgesics, and the claims also recite corticosteroids which is the narrower statement of the range/limitation. These claims also recite the broad recitation fungal infection therapies, and the claims also recite anti-fungals which is the narrower statement of the range/limitation.

5. Claims 14, 25, 71, 73, 75, 77, 79, 81, 83, 97, 104, and 111 recite analgesics twice.

only in marked up

6. Claim 43 recites the limitation "the freeze-dried powder" in line 13. There is insufficient antecedent basis for this limitation in the claim. Accordingly, claims 67-68, 104-110 have also been rendered indefinite.

7. The term "essentially every diluent" in claims 13 and 45 is a relative term which renders the claim indefinite. The term "essentially every diluent" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the "diluent particle comprising at least one embedded nanoparticulate drug particle having a surface modifier adhered to the surface of the drug particle" and "at least one embedded drug particle and a surface modifier," respective to claims 13 and 45, are rendered indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Claims 11-34, 40-41, 44-45, 47-48, 51-62, 69-96, 111-117 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Edwards et al (5,985,309; hereafter '309).

'309 discloses aerosol particle compositions that are less than 100 microns in diameter and have a surface modifier adsorbed thereon. The surface modifiers can be found at column 7, lines 55-63 and in the examples and are the same as those of the instant application as stated on page 26, line 10-page 27, line 28. '309 also discloses the spray-drying and freeze-drying the compositions. Example 14 discloses that the concentration of drug is within the instant ranges (i.e. 200 μg/5mg albuterol is equivalent to 40 mg/g).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 11-34, 40-41, 44-45, 47-48, 51-62, 69-96, 111-117 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5,985,309; hereafter '309).

'309 teaches aerosol particle compositions that are less than 100 microns in diameter and have a surface modifier adsorbed thereon. The surface modifiers can be found at column 7, lines 55-63 and in the examples and are the same as those of the instant application as stated on page 26, line 10-page 27, line 28. '309 also discloses the spray-drying and freeze-drying the compositions. Example 14 discloses that the concentration of drug is within the instant ranges (i.e. 200 μg/5mg albuterol is equivalent to 40 mg/g). The compositions of the instant claims and those of '309 do not appear to be different. Both are aerosol compositions comprising spray- or freeze-dried drug particles less than about 100 μm, and deliver an agent to the deep lung (C 9, L 59-63). Furthermore, '309 teaches that varying the spray drying parameters, the aerodynamic properties of the inhaled particles can be effectively controlled through, for example, adjusting the inlet temperature or the feed rate and pressure of the compressed air to alter particle size (C 27, L 12-31) resulting in particle sizes that provide optimal deposition within targeted sites within the respiratory tract.

12. Claims 11-34, 40-45, 47-48, 51-62, 65-96, and 97-117are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5,985,309; hereafter '309) in view of Liversidge et al (5,145,684; hereafter '684).

'309 is relied upon for all that it teaches as stated previously.

'684 teaches particle compositions that are less than 100 microns in diameter and have a surface modifier adsorbed thereon. The particles of '684 are for administration of drugs such as corticosteroids (known for treatment of asthma and allergies by administration in metered dose inhalers) and are produced by milling under non-pressurized conditions. After milling, the particles are separated from the milling dispersion using a sedimentation field flow fractionator. This appears to result in particles that are the same as those of the instant claims, absent a demonstration between using a sedimentation field flow fractionator and evaporation.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '309 and '684 to provide aerosol corticosteroid particle formulations that meet the limitations of the instant claims based upon the motivation that corticosteroids are used in metered dose inhaler aerosol formulations for treatment of asthma and allergies and that the rate of dissolution of a particulate drug can increase with increasing surface area, i.e., decreasing particle size, along with providing optimal deposition with targeted sites within the respiratory tract.

13. Claims 35-36, 49, 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al (5,985,309; hereafter '309) in view of Dalby et al (5,202,110; hereafter '110).

'309 is relied upon for all that it teaches as stated previously.

'110 is relied upon for teaching propellant metered dose inhalers where the propellant is a "non-CFC" propellant.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '309 with '110 to provide propellant metered dose inhalers where the propellant is a "non-CFC" propellant, thereby providing "environmentally friendly" propellant compositions of the '309 compositions that provide distribution to the deep tissues of the lungs.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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August 22, 2001